

Remarks/Arguments:

The applicants note with appreciation the Examiner's indication that claims 14-20 would be allowable if the rejection based on 35 U.S.C. § 112, second paragraph is overcome and claims 14-20 are rewritten to include the limitations of the base claim and intervening claims.

Claims 1-30 are pending in this application. First, the Office Action objects to the drawings because the two different introducers were not shown. Second, the Office Action rejects claims 14-20 for lack of antecedent bases with respect to "step (c)." Third, the Office Action rejects claims 1-13 and 21-27 based on U.S. Patent No. 5,609,627 to Goicoechea, et al. (Goicoechea) in view of U.S. Patent No. 5,817,101 to Fiedler (Fiedler). Fourth, and finally, the Office Action objects to claims 28-30 as dependent upon a rejected base claim. The applicants respectfully traverse each of these rejections, as further detailed below, and respectfully request re-examination of the application in light of the arguments and amendments herein.

Amendments to the Drawings:

In response to the Office Action's objection to the drawings for failure to show "the two different introducers," the applicants submit supplemental Figures 6A and 6B. The applicants respectfully request that these drawings be entered into the file. Figure 6A depicts a longitudinal cross section of a standard introducer of the prior art. Figure 6B depicts a detailed longitudinal cross section of the encircled portion of Figure 6A. The submitted Figures 6A and 6B represent no new matter because they find direct support in the specification of this application and because they were copied from patent application serial number 10/081,641 titled "METHOD AND APPARATUS FOR DEPLOYMENT OF AN ENDOLUMINAL DEVICE," by Haverkost et al. which was incorporated by reference into this application. The specification as originally filed referred to the title, inventor, and attorney docket number. As amended, the specification now recites the serial number of this application. An amendment to the description is also filed herewith for consistency.

The applicants respectfully submit that the specification, as amended, meets the requirements of 37 C.F.R. 1.83(a). The applicants therefore respectfully submit that the objection to the drawings should be withdrawn.

35 U.S.C. § 112, Paragraph 2

The Office Action rejects claims 14-20 for lack of antecedent bases with respect to "step (c)." The applicants have corrected a clerical error by amending dependent claims 14-20 so that claims 14-20 refer to, directly or indirectly, "step (b)" of claim 1 rather than "step (c)". The applicants respectfully submit that claims 14-20, as amended, are in condition for allowance.

35 U.S.C. § 103(a)

The Office Action rejects claims 1-13 and 21-27 under 35 U.S.C. § 103(a) based on U.S. Patent No. 5,609,627 to Goicoechea, et al. (Goicoechea) in view of U.S. Patent No. 5,817,101 to Fiedler (Fiedler). The applicants respectfully traverse the rejection and submit that claims 1-13 and 21-27 recite limitations neither taught nor suggested by Goicoechea or Fiedler taken individually or in combination.

Goicoechea discloses a method and apparatus for delivering a bifurcated endoluminal prosthesis. An embodiment disclosed by Goicoechea includes a modular prosthesis device comprising a body portion and two stump portions. Goicoechea does not disclose or suggest the delivery of a proximal end of a prosthesis prior to delivery of its distal end. Goicoechea also does not disclose or suggest the advantageous delivery of a second modular prosthesis component onto a first modular prosthesis component by first deploying the proximal end of the second modular prosthesis and afterwards deploying its distal end in overlapping engagement with the proximal end of the first modular prosthesis component.

Fiedler discloses fluid-actuated stent delivery systems. An embodiment disclosed by Fiedler is designed to deliver a stent device "such that the proximal portion at 82 is the first to be released and expand with the remainder following thereafter." Fiedler at col. 5, lines 63-65. Fiedler does not disclose or suggest a multi-component prosthesis device. Fiedler clearly does not disclose or suggest the advantageous delivery of a second modular prosthesis component onto a first modular prosthesis component by first deploying the proximal end of the second modular prosthesis component in the lumen and afterwards

deploying its distal end in overlapping engagement with the proximal end of the first modular prosthesis component.

The applicants' invention, as claimed, recites methods and systems for deploying a multi-part endoluminal device. The method comprises the steps of deploying a first portion of the device in the traditional, distal-end-first delivery, and reverse-deploying a second portion by anchoring its proximal end to the lumen wall first and then overlapping it with, and engaging it to, the first portion. Neither Goicoechea nor Fiedler, taken singly or in combination, teach a method for reverse deployment of a second device onto a previously forward-implanted first device. This inventive aspect of the applicants' method produces a number of advantages.

Among the advantages is the ability to manipulate the precise placement of **both** the proximal and distal ends of the entire multi-part endoluminal device. That is, the exact beginning point and ending point of the whole endoluminal passage defined by the multi-part device can be selected. Traditionally delivered multi-part devices generally require the implanting surgeon to estimate the best position for first attaching the second component at the distal end to the first component in order to achieve a desired proximal attachment location. The applicants' invention as claimed instead permits the implanting surgeon to first select and attach the proximal end of the second component to the lumen wall and then overlap the two devices as needed.

Another advantage of the applicants' invention as claimed is that it can reduce the large number of different sizes of each of the components that a surgeon must choose from to effect a successful device implantation. The increased ease with which the surgeon can fit the components together within the lumen geometry can simplify, and even reduce the time required for, the implantation procedure. Increasing interchangeability can also decrease overhead-related costs as fewer sizes need to be maintained in stock in anticipation of a procedure.

The claimed systems are adapted to carry out applicants' novel and non-obvious method. Independent claim 21 recites a combination of a first, forward-deploying introducer, loaded with a first endoluminal device, and a second, reverse-deploying introducer, loaded with a second endoluminal device adapted to engage the first endoluminal device. Although Goicoechea discloses essentially a forward-deploying introducer and Fiedler discloses essentially a reverse-deploying introducer, there is no suggestion to combine the structure disclosed in one reference with the structure disclosed in the other reference. It is respectfully submitted that it is applicants' own novel and non-

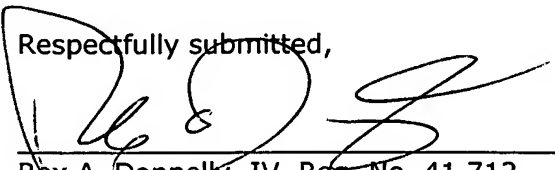
obvious method of reverse deploying a second stent onto a forward deployed first stent that provides the sole motivation for the claimed combination. As applicants have argued above, neither Goicoechea nor Fiedler, taken singly or in combination, suggests this method. Nor do Goicoechea or Fiedler, taken singly or in combination, supply an alternative motivation for the claimed combination. Therefore, the applicants respectfully submit that a person of ordinary skill in the art would not have been motivated to make the combination suggested by the Office Action as obvious, except in hindsight in light of the applicant's disclosure.

In *Ex parte Metcalf*, 67 U.S.P.Q.2d 1633 (May 2, 2003), the USPTO Board of Patent Appeals and Interferences stressed that there must be objective motivation to support an obviousness rejection. More specifically, the mere fact that teachings found in the prior art could be combined as proposed by an Examiner does not make the combination obvious "absent some teaching, suggestion or incentive supporting the combination." *Id.* at 1635 (citing *Carella v. Starlight Archery and Pro Line Co.*, 231 USPQ 644, 647 (Fed. Cir. 1986)). It is respectfully submitted that the Office Action has failed to identify any such teaching, suggestion, or incentive to support its proposed combination. Accordingly, it is respectfully submitted that claim 21 is patentable over the art of record. Likewise, it is respectfully submitted that claims 22-27, which ultimately depend from claim 21, are also patentable over the art of record.

Summary

In view of the arguments set forth above, the applicants respectfully submit that claims 1-30 are in condition for allowance. Early and favorable notification to this effect is respectfully requested.

Respectfully submitted,



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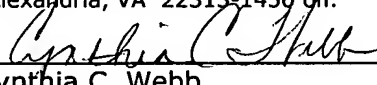
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Attachments: (1) Drawing Sheet

Dated: October 27, 2004

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Cynthia C. Webb

October 27, 2004

Appln. No.: 10/080,791
Amendment Dated October 27, 2004
Reply to Office Action of July 27, 2004

BSI-488US

Amendments to the Drawings:

The attached drawing sheet has been added.

Attachment